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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/015,202	11/05/2001	Alan H. Ostroff	032580.0045.CIP	7091

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EXAMINER	
DROESCH, KRISTEN L	

ART UNIT	PAPER NUMBER
3762	

DATE MAILED: 07/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/015,202	OSTROFF ET AL.	
	Examiner	Art Unit	
	Kristen Droesch	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *6/2/04 (amendment)*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *150-165* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *150-152,154-160,162 and 163* is/are rejected.

7)☒ Claim(s) *153,161,164 and 165* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *05 November 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Objections

1. Claim 153 is objected to because of the following informalities: "rhythm" is used interchangeably with "cardiac cycle". Appropriate correction is required.

2. Claims 164-165 are objected to because of the following informalities: Claim 164 concludes with a semicolon. Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claim 152 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5. Claim 152 recites the limitation "the device electrode" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claims 150-151, 155, 157-160, 162-163 are rejected under 35 U.S.C. 103(a) as being unpatentable over KenKnight (6,148,230) in view of Krasner (3,593,718).

Regarding clam 150, KenKnight shows a method comprising implanting a device having a housing (18) and containing circuitry, implanting at least one electrode (22, 24, 26) coupled to the device, wherein the at least one electrode is implanted to be non-vascular and non-cardiac (Fig. 1). Although KenKnight fails to show the circuitry is configured to provide a constant current output signal, attention is directed to Krasner, which teaches circuitry configured to provide a constant current output signal compensates for fibrotic growth on the electrode (Abs). Therefore, it would have been obvious to one with ordinary skill in the art at the time the invention was made to modify the device utilized in the method of KenKnight to include circuitry configured to provide a constant current output signal in order to compensate for fibrotic growth on the electrode as Krasner teaches.

With respect to claim 151, KenKnight shows the device further includes a device electrode (18) disposed on or making up part of the housing (Col. 4, lines 25-28).

Regarding claim 155, Krasner shows generating a monophasic constant current signal (Fig. 1).

With respect to claim 157, KenKnight shows a method comprising implanting a device (18), providing a lead system (20) having one or more electrodes (22, 24, 26), the lead system provided such that it is disposed internally to the patient without contacting the patient's heart, sensing an abnormality in the patient's cardiac rhythm using electrodes disposed internally to the patient but not contacting the patient's heart, at least one of the electrodes being part of the lead system; and discharging a signal from the device (18) to the patient (Col. 3, lines 41-62; Col. 4, lines 16-29; Fig. 1).

Although KenKnight fails to show the device is adapted to provide a constant current signal into the patient and discharging a constant current signal from the device to the patient, attention is directed to Krasner, which teaches a device adapted to provide a constant current signal into the patient and discharging a constant current signal from the device to the patient compensates for fibrotic growth on the electrode (Abs). Therefore, it would have been obvious to one with ordinary skill in the art at the time the invention was made to modify the method of KenKnight to include a device adapted to provide a constant current signal into the patient and discharging a constant current signal from the device to the patient in order to compensate for fibrotic growth on the electrode as Krasner teaches.

Regarding claim 158, KenKnight shows the lead system (20) is provided such that it does not reside in the patient's vasculature (Fig. 1).

With respect to claim 159, KenKnight shows the step of sensing an abnormality in the patient's cardiac rhythm makes use only of electrodes disposed outside of the patient's heart and vasculature (Col. 4, line 24-25; electrodes 22 and 24, electrodes 24 and 18, and electrodes 22 and 18).

Regarding claim 160, KenKnight shows discharging the signal is performed using two electrodes as anode and cathode (18 and 8, or 26 and 8), and a line drawn from the anode to the cathode would intersect the heart (Fig. 1).

With respect to claim 162, KenKnight shows the anode and cathode (18 and 8, or 26 and 8) are on opposing sides of the heart (Fig. 1).

Regarding claim 163, KenKnight shows the device (18) and the lead system (20) are disposed in the patient such that electrodes (22, 24, 26) in the lead system consist of electrodes disposed outside of the patient's heart and vasculature (Fig. 1).

8. Claims 154, and 156 are rejected under 35 U.S.C. 103(a) as being unpatentable over KenKnight (6,148,230) in view of Krasner (3,593,718), and further in view of Mulier (3,713,449). KenKnight and Krasner are as explained before. Although KenKnight and Krasner fail to teach the circuitry is adapted to provide two constant current electric signals in a biphasic waveform and the method comprises generating first and second constant current electric signals of opposing signs in a biphasic waveform, attention is directed to Mulier which teaches that it is well known to provide or generate two (first and second) constant current electric signals in a biphasic waveform (Tables III-IV). Therefore, it would have been obvious to one with ordinary skill in the art at the time the invention was made to modify the method of KenKnight and Krasner to provide or generate two (first and second) constant current electric signals in a biphasic waveform since Mulier teaches it is well known in the art to provide or generate constant current electrical signals in a biphasic waveform.

The functional language and statements of intended use have been carefully considered but are not considered to impart any further structural limitations over the prior art.

Response to Arguments

9. Applicant's arguments with respect to claims 150-165 have been considered but are moot in view of the new ground(s) of rejection.

Allowable Subject Matter

10. Claim 152 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim, and claim 151.

11. Claims 153 would be allowable if rewritten to overcome the objection for minor informality set forth in this Office action and to include all of the limitations of the base claim, and any intervening claims.

12. Claim 161 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

13. Claims 164-165 would be allowable if rewritten or amended to overcome the objection for minor informality set forth in this Office action.

Regarding claim 152, the prior art of record fails to teach or suggest a method comprising, implanting a device having a housing containing circuitry and including a device electrode disposed on or making up part of the housing, the circuitry configured to provide a constant current output signal, implanting at least one electrode coupled to the device, wherein the at least one electrode is implanted to be non-vascular and non-cardiac all in combination with treating tachycardia by forcing a constant current signal to pass through patient tissue between the device electrode and another implanted non-vascular and non-cardiac electrode.

With respect to claim 153, the prior art of record fails to teach or suggest a method comprising, implanting a device having a housing and containing circuitry, the circuitry configured to provide a constant current output signal, implanting at least one electrode coupled

to the device, wherein the at least one electrode is implanted to be non-vascular and non-cardiac all in combination with sensing a portion of the patient's cardiac cycle; categorizing the patient's cardiac cycle as acceptable or abnormal; and if the rhythm is abnormal, generating a constant current electric signal between implanted non-vascular and non cardiac electrodes.

Regarding claim 161, the prior art of record fails to teach or suggest a method comprising implanting a device adapted to provide a constant current signal into a patient, providing a lead system having one or more electrodes for the device, the lead system provided such that it is disposed internally to the patient without contacting the patient's heart, sensing an abnormality in the patient's cardiac rhythm using electrodes disposed internally to the patient but not contacting the patient's heart, at least one of the electrodes being part of the lead system, and discharging a constant current signal from the device to the patient using two electrodes as anode and cathode, where a line drawn from the anode to the cathode would intersect the heart, all in combination with the anode and cathode being both disposed outside of the heart.

With respect to claims 164-165, the prior art of record fails to teach or suggest a method comprising implanting a device containing circuitry and having a housing including an electrode in a patient, implanting at least one electrode coupled to the device, and treating tachycardia by generating a constant current signal between the device electrode and another electrode coupled to the device; all in combination with all the electrodes coupled to the device being disposed outside of the patient's vasculature and exclusive of the patient's heart.

Conclusion

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kristen Droesch whose telephone number is 703-605-1185. The examiner can normally be reached on 10:30-6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 703-308-5181. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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